

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

## PCT

### WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing

(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
PCT/CZ2004/000053

International filing date (day/month/year)  
31.08.2004

Priority date (day/month/year)  
02.09.2003

International Patent Classification (IPC) or both national classification and IPC  
A61K9/19, A61K47/00

Applicant  
PLIVA-LACHEMA A.S.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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10/569866

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/CZ2004/000053

**IAP2005-010711D 28 FEB 2006**

**Box No. I Basis of the opinion**

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
  - ☐ This opinion has been established on the basis of a translation from the original language into the following language, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - ☐ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material:
    - ☐ in written format
    - ☐ in computer readable form
  - c. time of filing/furnishing:
    - ☐ contained in the international application as filed.
    - ☐ filed together with the international application in computer readable form.
    - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

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**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

Novelty (N)	Yes: Claims	1-5
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	1-5
Industrial applicability (IA)	Yes: Claims	1-5
	No: Claims	

**2. Citations and explanations**

see separate sheet

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**Box No. VI Certain documents cited**

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**1. Certain published documents (Rules 43bis.1 and 70.10)**

and /or

**2. Non-written disclosures (Rules 43bis.1 and 70.9)**

see form 210

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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING  
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/CZ2004/000053

AP20 Rec'd PCT/PTO 28 FEB 2006

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following documents:

- D1: WO 94/12193 A (DEBIOPHARM S.A.; IBRAHIM, HOUSSAM; IRIE, TERUKO; MAUVERNAY, ROLLAND-YVE) 9 June 1994 (1994-06-09)
- D2: MATHÉ G ET AL: "Oxalato-platinum or 1-OHP, a third-generation platinum complex: an experimental and clinical appraisal and preliminary comparison with cis-platinum and carboplatinum" BIOMEDICINE AND PHARMACOTHERAPY, ELSEVIER, PARIS, FR, vol. 43, 1989, pages 237-250, XP002094674 ISSN: 0753-3322
- D3: DE 103 14 377 A1 (STADA ARZNEIMITTEL AG) 7 October 2004 (2004-10-07)

**Novelty:**

The present application does meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-5 is new in the sense of Article 33(2) PCT.

None of the cited prior art documents discloses a composition comprising the specific weight ratio as claimed in claim 1.

**Inventive step:**

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-5 does not involve an inventive step in the sense of Article 33(3) PCT.

The present problem to be solved is the provision of an oxaliplatin lyophilizate which is stable and which has an alcoholic sugar of non-animal origin as a carrier.

The document D1 is regarded as being the closest prior art to the subject-matter of claim 1 and 4, and discloses a composition of oxaliplatin lyophilizate in combination with an alcoholic sugar of non-animal origin such as a carrier (see in particular claim 7, examples and p. 4, 3rd § in D1).

The subject-matter of claim 1 therefore differs from this known oxaliplatin lyophilizate in that the weight ratio of oxaliplatin to the alcoholic sugar of non-animal origin is 1:3 to 1:7. However, the selected weight ratio does not seem to contribute to establish inventive step over D1, since no evidence over the importance of the selected weight

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International application No.

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ratio for the stabilizing characteristics of the composition is derivable from the present application. Thus, the solution proposed in claim 1 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT).

The same reasoning applies, mutatis mutandis, to the subject-matter of the corresponding independent claims 4, which therefore is also considered not inventive.

**Re Item VI**

**Certain documents cited**

**Certain published documents**

Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
DE-A-10314377	07.10.04	28.03.03	